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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/477,983 06/07/95 RUBIN

J 40399/321/NI

EXAMINER

SAUD, C

ART UNIT

PAPER NUMBER

7

1812

DATE MAILED:

04/19/96

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-2, 13-14 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 3-12, 15-20 have been cancelled.
3. ☒ Claims 13-14 are allowed.
4. ☒ Claims 1-2 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☒ The corrected or substitute drawings have been received on 6/7/95. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☒ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Part III DETAILED ACTION

This application is a continuation of USSN 08/106,775. Claims 3-12 and 15-20 have been cancelled. Claims 1-2 and 13-14 are pending in the instant application.

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed; for example, "An Epithelial Cell Specific Growth Factor, Keratinocyte Growth Factor (KGF)".

Claim Rejections - 35 USC § 112

2. Claims 1-2 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a human KGF having an apparent molecular weight of about 28 kDa as determined by migration in NaDodSo₄/PAGE, and a specific activity of about 3.4×10^4 to 3.2×10^5 units per milligram of protein, where one unit of activity is defined as that amount which causes half of the maximal possible stimulation of DNA synthesis in BALB/MK keratinocyte cells under standard assay conditions. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The instant claims are currently broader than the enabling disclosure. Both claims are drafted in such breadth that the claims cover all compositions containing a protein having a molecular weight of about 28 kDa and having human KGF specific activity in excess of 3.4×10^4 (claim 1) or 3.2×10^5 (claim 2) units per milligram of protein regardless of the process used to achieve the purification and regardless of

the degree of purity achieved. There is no evidence of record regarding the upper limit of specific activity for KGF. It is conceivable that the upper limit of activity may be 10 to 20 times higher than that achieved utilizing Applicants' process and therefore, the claims are broader in scope than warranted by the enabling disclosure. The specification has not provided guidance to the skilled artisan as to how to obtain KGF with a specific activity greater than what is disclosed. Future modifications to the protein may provide for a specific activity which is significantly greater than that which is disclosed in the instant specification, modifications for which there is no guidance in the specification. It would not be predicative that one of ordinary skill in the art could obtain KGF with an unlimited specific activity, such activity being encompassed by the claims. Nor does the specification disclose methods of purifying or obtaining KGF with a higher specific activity than that already described. Undue experimentation would be required by a person of ordinary skill in the art to obtain KGF with a specific activity that is greater than the activity disclosed in the specification because there is no guidance in the specification to enable one of ordinary skill in the art as to how a greater activity could be obtained. As mentioned previously, modifications of the protein could increase the activity of the protein, but the specification has not provided guidance as how to modify the protein to increase its specific activity. Different purification methods may be able to increase the specific activity of the protein, but additional methods are not provided in the specification. In conclusion, it is determined that it would require undue

experimentation to obtain KGF with a specific activity greater than what is disclosed in the specification and that claims to "a specific activity of at least about" are broader than the enabling disclosure for the reasons stated above, absent evidence to the contrary.

3. Claims 1 and 2 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Language of "a specific activity of at least about" does not provide an upper limit of activity. Because there is no upper limit of activity, one of ordinary skill in the art would not be able to determine the metes and bounds of the claimed invention and therefore, the claims are indefinite.

Allowable Subject Matter

4. Claims 13 and 14 are allowable over the prior art of record.

5. The following is an Examiner's statement of reasons for the indication of allowable subject matter: the identification, purification, and sequencing of KGF was first performed by the Applicants. KGF was not disclosed in the prior art until the work of the Applicants was first published (Science 245: 752-755, 1989), and therefore, the invention pertaining to claims 13 and 14 is free of the prior art.

Serial Number: 08/477,983
Art Unit: 1812

-5-

6. Claims 1 and 2 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 4PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Garnette D. Draper, can be reached on (703) 308-4232. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christine Saoud, Ph.D.



April 8, 1996



GARNETTE D. DRAPER
SUPERVISORY PRIMARY EXAMINER
GROUP 1800